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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/756,774	01/12/2004	Alan M. Ezrin	500862001810	5612

20872 7590 06/29/2006

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EXAMINER	
WEBMAN, EDWARD J	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 06/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/756,774	EZRIN ET AL.	
	Examiner	Art Unit	
	Edward J. Webman	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 April 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-27,32-71 and 73-75* is/are pending in the application.

4a) Of the above claim(s) *12-22 and 56-65* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23-26, 32-35, 66-71, 73-75* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims 23-27, 32-35, 66-71, 73-75 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Nowhere in the specification do applicants disclose support for the limitation "not transferred to the vascular system." The passages in the specification applicants cite for support retention in the airways and lung, but not to language excluding the vascular system.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 23-24, 26-27, 66-67, 69-70 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 98/00171 (WO '171).

WO '171 teaches treatment with compounds comprising chemically reactive derivatives of a thrombin inhibitor that can react with available reactive functionalities on blood components to form covalent linkages (abstract). Treatment with the conjugate to various blood components is disclosed (page 10 lines 17-21). Serum albumin and platelets, which applicants disclose [page 20 lines 4-31] as both a mobile and stationary pulmonary and blood components, are specified (page 5 line 28). Hydroxysuccinimide is is disclosed (page 7 line 13). An aerosol is specified (column 11 line 230). As to the

claimed reactive properties, the anticipatory method must possess them because it uses the same compound as claimed.

Applicants argue that WO '171 does not teach the limitation "wherein said therapeutic agent covalently bonds to the fixed pulmonary component and is not transferred to the vascular system." However, as cited above, WO '171 teaches binding to loci which applicants disclose are stationary pulmonary components.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 23-24, 26-27, 32, 66-67, 69-71 are rejected under 35 U.S.C. 102(a) as being anticipated by WO 99/24462 (WO '462)

WO '462 teaches treatment using a derivative of an RDG containing peptide including a reactive functional group. The compound or its conjugate can be administered (abstract). Maleimide is disclosed (page 9 line 28). An aerosol is specified (page 12 line 22). Serum albumin and red blood cells are disclosed (page 11 line 28-page 12 line 4). As to the claimed reactive properties, the anticipatory method must possess them because it uses the same compound as claimed. However, as cited above, WO '462 teaches binding to loci which applicants disclose (see first 102 rejection *supra*) are stationary pulmonary components.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 23-27, 66-70 and 23-27, 32-33, 66-71 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO '462 and WO '461 respectively in view of Edwards et al (US 5,874,064).

WO '462 and WO '461 are described above. Neither disclose dry powder inhalation.

Edwards et al teach inhalation of particulates comprising a therapeutic agent for enhanced delivery (abstract). Any of a variety of actives is disclosed, including peptides (column 10 lines 1-5).

It would have been obvious to one of ordinary skill to use the Edwards et al particulates in the treatments of WO '462 and WO '461 to achieve the beneficial effect of enhanced delivery.

Applicants argue that neither of the primary references teaches the now claimed limitation. However, contrary to applicants' assertion, they both teach binding to loci which applicants disclose as stationary pulmonary components.

Claims 33-35, 73-75 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the compounds of examples 17 and 18, does not reasonably provide enablement for any antihistamine. The specification does not

enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. Applicants describe how to make the particular compounds cited above, but do not show how to make any other maleimido derivative of an antihistamine. In particular, applicants only disclose where the maleimido functionality is attached for the above cited compounds.

Applicants argue there is sufficient disclosure for any antihistamine. In examples 17 and 18 applicants activate the nitrogen in the 1 position of the piperidine and piperazine rings respectively by removing the ethoxyacetic acid and carboxylic acid ethyl ester moieties respectively, then reacting the exposed nitrogen with methyl chlorexthoxy acetate and maelimidopropylamine. However, clemizole, also an antihistamine, has no such nitrogen to expose by activation. Applicants do not appear to be enabled for this compound.

No claims allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward J. Webman whose telephone number is 571-272-0633. The examiner can normally be reached on M-F from 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, J Richter, can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

EDWARD J. WEBMAN
PRIMARY EXAMINER
GROUP 1500